FEB 2 4 2006

K051137

510(k) Summary

General Company Information

Name TechDevice Corporation

Address 650 Pleasant Street
Watertown, MA 02472

Contact Person: Leigh Hayward

Telephone: 617-972-5808

General Device Information

Product Name: TechDevice Percutaneous Occlusion Balloon Catheter

Common Name: Vascular occlusion balloon catheter

Classification: Catheter, Intravascular Occluding, Temporary (Class II); MJN / 21 CFR 870.1250

Predicate Devices Equalizer Balloon Catheter (K021721)
Boston Scientific Corporation
Natick, MA 01760

Product Description:
The occlusion balloon catheter consists of a latex balloon (outside diameter 11mm, 15mm, 18mm or 27mm) mounted on the distal end of a 5 French catheter shaft (45cm – 100cm in length). The dual-lumen catheter shaft terminates in a proximal molded bifurcation attached to luer connectors. The hub labeled "Distal" connects to the distal lumen which passes completely through the catheter and can be used for catheter placement over a guidewire, or fluid infusion into the vessel. The second hub, labeled "Balloon", terminates under the balloon via an opening skived into the extrusion. This is used for balloon inflation.

Indications for Use:
The TechDevice Percutaneous Occlusion Balloon Catheter is for temporary vessel occlusion, where the stoppage of blood flow is desirable. This device is not indicated for neuro, or cardiac use

Safety and Performance:
Substantial equivalence for this device was based on a comparison of labeling, physical and performance design characteristics as compared to the predicate device, as well as on the results of comparative bench testing. Comparative performance testing included tensile strength (balloon-to-shaft and hub/tube-to-shaft), balloon burst testing and balloon multiple inflation testing.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the TechDevice Percutaneous Occlusion Balloon Catheter has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2006

TechDevice Corporation
c/o Mr. Leigh Hayward
Director of Technical Operations
650 Pleasant St.
Watertown, MA 02472

Re: K051137
TechDevice Percutaneous Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II
Product Code: MJN
Dated: February 10, 2006
Received: February 13, 2006

Dear Mr. Hayward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: TechDevice Percutaneous Occlusion Balloon Catheter

Indications for Use:

The TechDevice Percutaneous Occlusion Balloon Catheter is for temporary vessel occlusion, where the stoppage of blood flow is desirable. This device is not indicated for neuro, or cardiac use.

Prescription Use X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K05 1137